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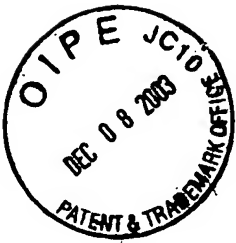
Serial Number: **10/701,883**

Filing Date: **November 5, 2003**

Title: **VERTEBRAL BODY REPLACEMENT AND METHOD OF USE**

Our Reference Number: **M112 1071.1**

Information Disclosure Statement  
Forms PTO-1449  
Copies of References A-BM  
Return Postcard



**PATENTS**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: )  
                  **MUHANNA, ET AL.** )  
Serial No:           **10/701,883** )  
Filed:               **November 5, 2003** )  
For:   **VERTEBRAL BODY REPLACEMENT AND METHOD OF USE**

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

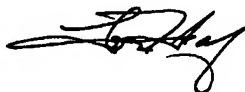
Applicant hereby voluntarily discloses the items listed on the attached Form PTO-1449 to the Assistant Commissioner for Patents. Copies of items A-BM are enclosed herewith.

Applicant further reserves the right to establish the patentability of the claimed invention over any of the listed information should they be applied as references, and/or to prove that some of the cited information may not be prior art, and/or to prove that some of the cited information may not be enabling for the teachings they purport to offer. This statement further should not be construed as a representation that an exhaustive search has been made, or that the information cited herewith is material, or that there does not exist information more material to the examination of the present Application. The Examiner is specifically requested not to rely solely on the information submitted herein. On the contrary, the Examiner is requested to conduct an independent and thorough review of the information, and to form independent opinions as to their significance.

It is respectfully requested that the Examiner initial and return copies of the enclosed PTO-1449 and to indicate in the official file wrapper of the above-identified patent application that each item of the cited information has been considered.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to account no. 09-0528.

Respectfully submitted,

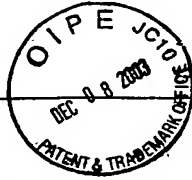


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Date: December 2, 2003

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Docket No.: **M112 1071.1**



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Form PTO-1449  INFORMATION DISCLOSURE CITATION  (Use several sheets if necessary)	Attorney Docket No. <b>M112 1071.1</b>	Serial No. <b>10/701,883</b>
	Applicant <b>Muhanna et al.</b>	
	Filing Date <b>November 5, 2003</b>	Group

## U.S. PATENT DOCUMENTS

Examiner Initials	Item	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	A	US 2001/0039458	11/01	Boyer II et al.	623	23.63	
	B	3,875,595	04/75	Froning	3	1	
	C	4,349,921	09/82	Kuntz	3	1	
	D	5,314,477	05/94	Marnay	623	17	
	E	5,609,636	03/97	Kohrs et al.	623	17	
	F	5,674,296	10/97	Bryan et al.	623	17	
	G	5,776,196	07/98	Matsuzaki et al.	623	17	
	H	6,096,080	08/00	Nicholson et al.	623	17	
	I	6,140,452	10/00	Felt et al.	528	60	
	J	6,146,422	11/00	Lawson	623	17.16	
	K	6,395,032	05/02	Gauchet	623	17.12	

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	L	WO 99/11203	03/99	PCT	A61F2	44		

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

	M	Experience and Short-Term Results with No-React Cardiovascular Implants – Chapter 15 – Advances in Anticalcific and Antidegenerative Treatment of Heart Valve Bioprstheses, First Edition, S. Milo, Y Bar-El, V. Kertsman, S. Sawaed, A. Hoffman, Silent Partners, Inc, Austin, 1997
	N	Unsurpassed Cytocompatibility Carotid and Peripheral Vascular Patch – Shelhigh No-React VascuPatch – Shelhigh, Inc.
	O	Shelhigh No-React – Pericardial Patch – Clinical Results – Shelhigh, Inc. - 0318

\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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**November 5, 2003**

Group

## U.S. PATENT DOCUMENTS

Examiner Initials	Item	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	P	4,479,491	10/84	Martin	128	92	
	Q	4,878,915	11/89	Brantigan	623	17	
	R	5,320,644	06/94	Baumgartner	623	17	
	S	5,397,364	03/95	Kozak et al.	623	17	
	T	5,499,984	03/96	Steiner et al.	606	80	
	U	5,782,919	07/98	Zdeblick et al.	623	17	
	V	5,865,848	02/99	Baker	623	17	
	W	6,004,326	12/99	Castro et al.	606	99	
	X	6,120,506	09/00	Kohrs et al.	606	80	
	Y	6,368,325	04/02	McKinley et al.	606	99	
	Z	6,520,967	02/03	Cauthen	606	99	

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

AA	Shelhigh DuraShield - No-React Treated, Dural Repair Patch - Shelhigh, Inc. - 0318
AB	No-React Detoxification Process: A Superior Anticalcification Method for Bioprostheses Abolhoda, M.D. et al. - 1996 - The Society of Thoracic Surgeons - Published by Elsevier Science, Inc. - Pages 1724-1730
AC	Calcification of Bovine Pericardium: Glutaraldehyde Versus No-React Biomodiciation - Abolhoda, M.D. et al. - 1996 - The Society of Thoracic Surgeons - Published by Elsevier - Pages 169-174

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Examiner Initials	Item	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AD	5,425,772	06/95	Brantigan	623	17	
	AE	5,693,100	12/97	Pisharodi	623	17	
	AF	5,755,798	05/98	Papavero et al.	623	17	
	AG	5,776,197	07/98	Rabbe et al.	623	17	
	AH	5,916,267	06/99	Tienboon	623	17	
	AI	5,961,554	10/99	Janson et al.	623	17	
	AJ	5,989,291	11/99	Ralph et al.	623	17	
	AK	6,030,390	02/00	Mehdizadeh	606	84	
	AL	6,033,438	03/00	Bianchi et al.	623	17	
	AM	6,056,749	05/00	Kuslich	606	61	
	AN	6,059,790	05/00	Sand et al.	606	99	

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

AO	Construction Factors Influencing The Shelhigh Porcine Bioprosthesis – Chapter 18 – Advances in Anticalcific and Antidenerative – Treatment of Heart Valve Bioprostheses, First Edition, edited by Shlomo Gabbay, M.D., David J. Wheatley, M.D., Silent Partners, Inc., Austin, 1997
AP	Structure of The Human Intervertebral Disk – Diwan et al. – Current Concepts in Intervertebral Disk Restoration – Pages 454-464
AQ	REVIEW – The Artificial Disc: Theory, Design and Materials – Qi-Bin Bao et al. - Biomaterials 1998 – Pages 1157-1167

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**U.S. PATENT DOCUMENTS**

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	AR	4,599,086	07/86	Doty			
	AS	4,834,757	05/89	Brantigan			
	AT	5,484,437	01/96	Michelson	606	61	
	AU	5,722,977	03/98	Wilhelmy	606	84	
	AV	6,283,966	9/01	Houfburg	606	61	

**FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	Shelhigh No React Patch – Page 1 of 1 – 12/6/00 – <a href="http://www.cosmotec.com/products/cs/shelhigh/e-shelhigh.htm">http://www.cosmotec.com/products/cs/shelhigh/e-shelhigh.htm</a>
	AX	Pelvicol Acellular Collagen Matrix – Surgical Innovations Tissue Solutions – BARD - brochure
	AY	Shelhigh, Inc. – Handling and Instruction for Use – No-React/Detoxified/Dura Shield - Product No. 555-DS
	AZ	Tsantrizos et al., <i>A COMPARATIVE BIOMECHANICAL STUDY OF POSTERIOR LUMBAR INTERBODY FUSION IMPLANTS</i> , 1997 Masters Thesis, Orthopaedic Research Laboratory, Division of Orthopaedic surgery McGill University, Montreal, Qc, Canada, The Uniformed Services, University of the Health Sciences, Bethesda, Maryland, U.S.A.
	BA	Collis et al., <i>Anterior Total Disc Replacement: A Modified Anterior Lumbar Interbody Fusion</i> , Lumbar Interbody Fusion, Chapter 13, pages 149-152.

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U.S. PATENT DOCUMENTS					
Examiner Initials	Item	Document Number	Date	Name	Class Subclass Filing Date If Appropriate
FOREIGN PATENT DOCUMENTS					
		Document Number	Date	Country	Class Subclass Translation Yes No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)					
	BB	Medical Multimedia Group, <i>A Patient's Guide to Low Back Pain</i> , <a href="http://www.sechrest.com/mmg/back/backpain.html">www.sechrest.com/mmg/back/backpain.html</a> , pages. 1-15, 7/14/00.			
	BC	Northwest Spine Surgery, <i>BAK Interbody Fusion</i> , <a href="http://www.backsurgery.com/bak1.htm">www.backsurgery.com/bak1.htm</a> , pages 1-2, ©1998.			
	BD	J. Flood – <i>Titanium cage lumbar interbody fusion</i> , © 1997, 1998 – <a href="http://www.irmc.org/about/ortho/qa_titanium.html">http://www.irmc.org/about/ortho/qa_titanium.html</a> , 5/22/00.			
	BE	Sulzer Spine-Tech – The BAK™ Patient Information, <i>An Innovative Approach to Surgical Spinal Treatment</i> , <a href="http://www.spine-tech.com/BAK-IPSIndex.html">http://www.spine-tech.com/BAK-IPSIndex.html</a> , 5/22/00.			
	BF	Sulzer Spine-Tech – The BAK™ Patient Information, <i>About BAK</i> , pages 1-2, <a href="http://www.spine-tech.com/BAK-IPSBKTechnology.html">http://www.spine-tech.com/BAK-IPSBKTechnology.html</a> , 5/22/00.			
	BG	Sulzer Spine-Tech – The BAK™ Patient Information, <i>How BAK Works</i> , <a href="http://www.spine-tech.com/BAK-IFSHowBAKWorks.html">http://www.spine-tech.com/BAK-IFSHowBAKWorks.html</a> , 5/22/00.			
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## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

	BH	Sulzer Spine-Tech – The BAK™ Patient Information, Clinical Results, Prospective Multi-Center Clinical Trial of the BAK™ Fusion System, pages 1-18, <a href="http://www.spine-tech.com/BAK-IFSClinicalResults.html">http://www.spine-tech.com/BAK-IFSClinicalResults.html</a> , 5/22/00.
	BI	Dimar et al., <i>Posterior Lumbar Interbody Cages Do Not Augment Segmental Biomechanical Stability.</i>
	BJ	Sengupta et al., <i>Biomechanical Comparison of Stability Provided by Rectangular vs Cylindrical Interbody Fusion Cages.</i>
	BK	Shelhigh Porcine Pulmonary Valve Conduit, No React Treated Clinical Case History
	BL	Workshop on No-React Bioprostheses, Brussels Hilton Hotel, 9/23/98, 12 <sup>th</sup> EACTS Annual Meeting, Moderator: Dr. Shlomo Gabbay.
	BM	Manufacturers of No-React Cytocompatible Bioprostheses and Other Tissue Products with Excellent Durability, Shelhigh, Inc.

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